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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,440	07/01/2003	Neil Berinstein	API-02-11-US	1959

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/611,440	BERINSTEIN ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,4-6,9,10,21,24-26,29,30,44,47-53,59,62-65 and 67-69* is/are rejected.

7)☒ Claim(s) *11,14-16,19,20,40-43,54,57,58 and 66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,4-6,9-11,14-16,19-21,24-26,29,30,40-44,47-49,52-54,57-59 and 62-69.

DETAILED ACTION

Claims 67-69 have been added. Claims 1, 4-6, 9-11, 14-16, 19-21, 24-26, 29, 30, 40-44, 47-49, 52-54, 57-59 and 62-69 are pending and under consideration.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/394,346, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The '346 application fails to provide a description of the instant peptides of SEQ ID NO: 23-32, 43-62, 71-90, 91-110 which result from administration of the claimed vector comprising SEQ ID NO:1. Therefore, claims 67-69 will be given the effective filing date commensurate with 60/394,503, filed 7/9/2002 which disclose said peptides on page 50.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1, 4, 5, 21, 24, 25, 26, 29, 30, 44, 47 and 48 under 35 U.S.C. 103(a) as being unpatentable over Gish et al (U.S. 6,780,586, reference of the IDS filed August 16, 2006) in view of Ghose et al (Human Gene Therapy, 2000, Vol. 11,pp. 1289-1301, cited in a previous Office action) is maintained for reasons of record. Claims 64 and 67-69 are rejected for the same reasons of record.

It is noted that the phrase "wherein administration of the vector to a mammal induces a T-cell response against at least one peptide selected from the group consisting of SEQ ID NO:" 23-32, 43-62, 71-80, 91-110 is not given patentable weight when comparing the claims to the prior art as it simply expresses the intended result of a process step positively recited, see MPEP 2111.04.

Gish et al teach a method of eliciting an immune response in an individual comprising the administration of a nucleic acid comprising a sequence encoding BFA4 (column 3, lines 41-48). SEQ ID NO:1 of Gish et al is identical to the instant SEQ ID NO:1. Gish et al do not teach a pox virus expression vector comprising the sequence encoding BFA4.

Ghose et al teach that canary pox vector are attractive platforms for expression of immunotherapeutic genes in various vaccination platforms and that canary pox or ALVAC vectors are able to infect a wide variety of cell types with a high efficiency of infection, the vectors can accommodate large inserts, the vectors are not mutagenic to the cell they infect, and in addition the vectors are replication defective in non-avian cells. (page 1290, first column, third full paragraph). Ghose et al teach that use of canary pox virus in cancer immunotherapy is becoming more widespread and that recombinant ALVAX vectors encoding tumor antigens are able to effectively infect antigen-presenting cells thereby causing stimulation of T cells, including CTL in humans (page1290, first column to second column, bridging paragraph). Gosh et al teach a greater anti-tumor response in mice vaccinated with an ALVAC vector additionally expressing B-7 and Il-12 respectively (page 1296, second column, top paragraph). It would be inherent in the expression vector rendered obvious by the combination of Gish et al and Ghose et al that the administration of the vector to a mammal would induce a T cell response against at least one peptide selected from the group consisting of SEQ ID NO: 23-32, 43-62, 71-80, 91-110 because the response is an inherent feature of the recognition of the immune system of the mammal to the exogenous protein of SEQ ID NO:1.

It would have been prima facie obvious at the time that the claimed invention was made to administer a canary pox vector encoding BFA4 to evoke a T cell response. One of skill in the art would have been motivate to do so by the teachings of Ghose et al on the advantages of a canary pox vector for the administration of antigens. One of skill in the art would have been further motivated to provide the vector with a nucleic acid encoding B7 or Il-12 because ALVAC expression of said nucleic acids

Applicant argues that the mere fact that the prior art can be modified to produce the claimed vectors does not make the modification obvious without teachings in the prior art which suggest such a modification. Applicant is referred to the teachings of Ghose et al regarding the improvements afforded to cancer immunotherapy by use of canarypox or ALVAC vectors as stated above.

Claims 1, 4, 5, 21, 24, 25, 26, 29, 30, 44, 47, 48, 59, 62-64 and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gish et al and Ghose et al as applied to claims 1, 4, 5, 21, 24, 25, 26, 29, 30, 44, 47, 48, 64 and 67-69 above, and further in view of Paoletti et al (U.S. 5,833,975)

Claims 21 and 59 embody the expression vectors of claim 1 and claim 44, respectively further comprising at least one nucleic acid sequence encoding a co-stimulatory component.

Paoletti et al teach recombinant poxviruses comprising an exogenous DNA sequence encoding a cytokine and a tumor-associated antigen, wherein the poxvirus is ALVAC or attenuated canarypox (claim 1).

It would have been prima facie obvious at the time that the claimed invention was made to modify the vector rendered obvious by the teachings of Gish et al and Ghose et al to further comprise a DNA encoding a cytokine in addition to the BFA4 tumor associated protein. One of skill in the art would have been motivated to do so by the knowledge that cytokines further stimulate an immune response to a vaccine protein, and the teachings of Paoletti et al regarding the pox viruses which express both a tumor antigen and a cytokine.

Claims 1, 4-6, 9, 10, 21, 24-26, 29, 30, 44, 47-49, 52, 53, 59, 62-65 and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gish et al, Ghose et al and Paoletti et al as applied to claims 1, 4, 5, 21, 24-26, 29, 30, 44, 47, 48, 59, 62-64 and 67-69 above, and further in view of McArthur et al (U.S. 7,217,421).

The combination of Gish et al, Ghose et al and Paoletti et al render obvious the claims to the extent that the pox virus expresses the nucleic acid encoding BFA4 as well as a cytokine. The combination of prior art references do not specifically suggest a poxvirus expression BFA4, a cytokine and an additional tumor antigen.

McArthur et al teach cells transduced with multiple tumor-associated antigens as well as a cytokine (column 7, lines 5-7), wherein the vector that expresses said nucleic acids is a pox viral vector (column 7, lines 1-4). McArthur et al teach that a combination of tumor-associated antigens can be used to administer to all patients who may have varied cancer gene expression, and to prevent immunological escape by cancer cells within an individual patient (column 17, lines 60-67).

It would have been prima facie obvious at the time that the claimed invention was made to include DNA encoding multiple tumor antigens in addition to DNA encoding BFA4 and a cytokine within he pox viral vectors rendered obvious by the combination of Gish et al, Ghose et an and Paoletti et al. One of skill in the art would have been motivated to include other tumor antigens by the teachings of McArthur regarding the avoidance of escape mutants within an individual patient and the greater utility of a vaccine comprising multiple antigens in administration to a group a cancer patients harboring cancers with varying gene expression.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicants argument.

Claims 11, 14-16, 19, 20, 40-43, 54, 57, 58 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643